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NormaTec MVP

JAN - 4 2012

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Date Prepared: December 12, 2011

Name of Device and Name/Address of Sponsor

NormaTec MVP

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NormaTec Industries, LP
44 Glen Avenue
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Contact Person: Laura F. Jacobs, M.D., Ph.D.

Common or Usual Name

Powered inflatable tube massager

Classification Name

Powered inflatable tube massager
IRP
21 C.F.R. § 890.5650

Predicate Devices

NormaTec PCD (K013436)
Telebrand Air Press Massager (K032505)
Pneumatic Peripheral Circulation Improvement Device (PPCID) (K000655)

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Intended Use / Indications for Use

The NormaTec MVP is an air pressure massager intended to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas.

Technological Characteristics

The NormaTec MVP is a powered inflatable tube massager. It is intended for medical purposes, such as to relieve minor muscle aches and pains and to increase circulation to the treated areas. It simulates kneading and stroking of tissues with the hands by use of an inflatable pressure cuff. The device is to be used by people who are in good health.

The NormaTec MVP consists of an air compressor with a manual pressure adjustment bleed-valve, an inflatable appliance (boot or arm sleeve), plastic air tubing connecting the device to the appliances, and an AC/DC adaptor with power cord. The appliance is divided into 5 segments, with a single tube leading from each segment to the tubing connector on the device.

Performance Data

The NormaTec MVP underwent safety testing and quality assurance testing. In all instances, the NormaTec MVP functioned as intended and the results observed were as expected. The NormaTec MVP is in compliance with electrical safety and electromagnetic compatibility standards IEC 60601-1 and IEC 60601-1-2.

Substantial Equivalence

The NormaTec MVP is substantially equivalent to its predicates because it has the same intended use, similar indications for use and technological characteristics. The NormaTec MVP and the predicates, the Telebrand Air Press Massager (K032505) and the Pneumatic Peripheral Circulation Improvement Device (PPCID) (K000655), are intended to temporarily relieve minor muscle aches, pains, and to temporarily increase circulation to the treated areas.

NormaTec's MVP has very similar components as its predicate devices and very similar principles of operation. Each device consists of an electrically generated source of compressed air, tubing to convey the pressurized air to the inflatable appliance, and control of pressure applied cyclically. Several of the components of the MVP are identical to its predicate, the NormaTec PCD.
The minor technological differences between the MVP and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the MVP is as safe and effective as the predicate device. Thus, the MVP is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN - 4 2012

NormaTec Industries, LP
% Hogan Lovells US LLP
Mr. Jonathan Kahan
555 Thirteenth Street, NW
Washington, District of Columbia 20004

Re: K112890
Trade/Device Name: NormaTec MVP
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered inflatable tube massager
Regulatory Class: Class II
Product Code: IRP, JOW
Dated: December 12, 2011
Received: December 12, 2011

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K112890

Device Name: NormaTec MVP

Indications for Use:

The NormaTec MVP is an air pressure massager intended to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas.

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112890